

Remarks

Claims 1, 2, 4, 9, 11, 12 and 43 are currently in the present application.

All claims have been rejected, under 35 USC § 103, based on the Nutramex Laboratories '816, Florio '715, Martino '692, Burger '919, Morad '594 and Versalla '878 references.

The claims of the present application have been amended to more specifically define the sweetener component of the beverage; that component must include erythritol in an amount such that it constitutes from about 0.25% to about 10% of the composition. It also must include an edible coloring agent. Antecedent basis is found in the present application at page 14, line 29; no new matter is included by virtue of this amendment. The claims have also been amended to specify that a coloring agent is present (basis at page 27, lines 19 *et seq*) and to define the maximum carbohydrate level in the compositions (basis at page 14, line 29).

None of the references cited by the Examiner disclose or suggest a beverage which combines a chondroprotective agent (and particularly not the three specific materials defined in claim 4) with erythritol. The Examiner states that the use of erythritol does not provide any unexpected results. In fact, the use of erythritol does provide unexpected results in the context of the beverage compositions of the present invention.

First, erythritol provides a color stability benefit to the beverage compositions. Attached is a Declaration under 37 CFR 1.32 of Robert J. Sarama. In the declaration, Mr. Sarama describes experiment which shows that a composition containing about 5% erythritol exhibited superior color stability when compared to a composition which included no erythritol. This benefit could not have been derived from the prior art references cited by the Examiner.

Further, erythritol uniquely has properties which make it useful in the compositions of the present invention (as opposed to other conventional non-caloric sweeteners). Specifically, in a beverage composition, sweeteners generally have to be used at higher levels. This is particularly true with sugar alcohols, such as erythritol. The use of such higher levels of sweeteners in a full beverage composition can cause the consumer gastrointestinal distress, which obviously is

something the producer of the beverage would rather avoid. Since, erythritol is a small molecule, it passes through the body relatively easily and intact and, as a result, it does not cause the gastrointestinal distress frequently found with other sugar alcohol sweeteners. Thus, it cannot be said that all non-caloric sweeteners are equivalent and that the substitution of erythritol for another known sweetener is equivalent or obvious. In fact, the use of erythritol presents particular benefits (as defined above) in the context of a sports beverage composition (of which large quantities are frequently consumed in a short period of time), which is what is claimed in the present application. In addition, the use of erythritol provides a desirable textural quality (a desirable mouthfeel) to the beverage, which is not obtained when other sweeteners are used. All of these benefits are confirmed in the attached Sarama Declaration. Accordingly, the compositions claimed in the present application would not have been obvious based on the references cited by the Examiner, and it is respectfully requested that the § 103 rejection be withdrawn.

In light of the foregoing amendments and remarks, and the attached Sarama Declaration, it is submitted that the claims currently pending in the present application are now in form for allowance. Accordingly, reconsideration and allowance of the claims as amended herein, are earnestly solicited.

Respectfully submitted,

Matthew Thomas Heisey et al

By



Steven J. Goldstein

Registration No. 28,079

FROST BROWN TODD LLC

2200 PNC Center

201 East Fifth Street

Cincinnati, Ohio 45202-4182

(513) 651-6131

Date 29 February 2008

PATENT
Attorney Docket 0106281/0528224

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Matthew Thomas Heisey et al : Confirmation No: 1681
Serial No. 09/759,965 : Group Art Unit: 1623
Filed: January 12, 2001 : Examiner: Crane, Lawrence E.
For: Low Carbohydrate Compositions, Kits Thereof, And Methods of Use

Declaration of Robert J. Sarama 37 CFR 1.132

Robert J. Sarama says the following:

1. Statements in this declaration are known to be true or, if made on information and belief, as believed to be true.
2. I understand that willful false statements or the like made in this declaration, can subject me to fine or imprisonment or both, under 18 USC 1001, and can jeopardize the validity of any patent that issues on the above patent application.
3. I have a BS degree in chemical engineering from the New Jersey Institute of Technology, and am currently studying for my Ph.D. at the University of Cincinnati.
4. I have extensive experience in the formulation of nutritional food products and, particularly beverage products. I worked from 1977 to 2005 at The Procter & Gamble Company, holding a variety of product formulation and supervising positions, including five years in the Food and Beverage Technology Division.

Serial No. 09/759,965

Since January, 2005, I have been at Sunny Delight Beverage Company holding the position of Innovation Manager, as well as the position of Chief Scientist at The Elations Company. I am a named inventor on 13 US patents and have 14 US patent applications pending.

5. I am familiar with the above patent application, as well as the rejections made by the Examiner of that patent application.

6. Elations is a nutritional beverage manufactured and sold by Sunny Delight which falls within the scope of the above patent application.

7. Historically, erythritol, an artificial sweetener, has been used in low calorie Elations at a level of 2%. Some time ago, we reformulated the product including the reduction of erythritol to 1/10 its original level and the elimination of high fructose corn syrup. Upon these changes, a reduction in product color stability was observed. Since color stability is directly linked to vitamin C stability, this change suggested that either the erythritol or sugar were an important part of the product's stability matrix.

8. To examine the potential importance of erythritol, I conducted a simple experiment to determine if erythritol was protective of Elations stability by reducing the detrimental impact of metal ions (known to destabilize vitamin C).

9. The experiment:

Obtained 3 bottles of nationally produced Elations (code KF 1319).
To one bottle, 0.065 grams of steel wool was added (iron/ion source).
To the next bottle, 5.0 grams of erythritol and 0.066 grams of steel wool were added.
The third bottle was used as the control

10. All three bottles were placed in a 73 deg F controlled temperature room under lighted conditions for four days. At the conclusion of the fourth day the samples were analyzed for color and vitamin C changes. Data is as follows:

Serial No. 09/759,965


<u>Sample</u>	<u>Hunter Color (L/a/b)</u>	<u>Hunter a Color</u>	<u>Vitamin C (ppm)</u>
Control	39.34/43.77/55.60	43.77	610
Erythritol/Iron	47.01/10.43/36.38	10.43	576
Iron only	55.09/-10.61/37.28	-10.61	341

11. As one can see, there are significant difference in the product's "a" color (+a, red to -a, green) color and vitamin C retention. The product without erythritol actually turned green, which is caused by the deprotonation of vitamin C. These protons react with the double bonded nitrogen group (azo) of the FD&C Red #40 dye. As this happens, the red 40 becomes colorless. The product turns green because of the products amber base color and the presence of FD&C Blue #1.

12. Because an iron source was directly added, this suggests that erythritol either runs interference with the detrimental effect of iron on vitamin C or perhaps chelation potential. In any event, the presence of erythritol enhances the color stability of the product.

13. In addition, erythritol uniquely has properties which make it useful in the compositions of the present invention, as opposed to other non-caloric sweeteners. Specifically, in a beverage composition, sweeteners generally have to be used at higher levels. This is particularly true with sugar alcohols, such as erythritol. The use of such high sweetener levels in a full beverage composition can cause the consumer gastrointestinal distress, which obviously the manufacturer of the beverage would rather avoid. Since erythritol is a small molecule, it passes through the body relatively easily and intact and, as a result, it does not cause the gastrointestinal distress frequently found with other sugar alcohol sweeteners.

Further deponent sayeth not.


Robert J. Saranya
Date: 2/28/08